

K053194

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**SECTION 5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

MAR 9 2006

**5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**APPLICANT** Biosense Webster, Inc.  
3333 Diamond Canyon Rd.  
Diamond Bar, CA 91765

**TRADE NAME:** NOGA™ XP Cardiac Navigation System with QwikMap™ Software

**COMMON NAME:** Cardiac Mapping System

**CLASSIFICATION NAME:** Programmable diagnostic computer

**DEVICE CLASSIFICATION:** Class II, 21 CFR §870.1425

**PRODUCT CODE** 74 DQK - computer, diagnostic, programmable

**PREDICATE DEVICE:** NOGA™ Cardiac Navigation System and the CARTO™ XP QWIKMAP™ EP Navigation System

**MANUFACTURER** Biosense Webster (Israel) Ltd.  
POB 2009  
Tirat HaCarmel, 39120  
Israel

**SUBSTANTIALLY EQUIVALENT TO:**

The NOGA™ XP Cardiac Navigation System is substantially equivalent to the NOGA™ Cardiac Navigation System cleared for marketing under K000332 and to the CARTO™ XP QWIKMAP™ EP Navigation System cleared for marketing under K020863.

**DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:**

The NOGA™ XP Cardiac Navigation System with QwikMap™ Software is a modification of the NOGA™ Cardiac Navigation System cleared for marketing under K000332. Like the predicate device, the NOGA™ XP System is a computerized electromechanical mapping system designed to acquire, analyze, and display electromechanical maps of the heart in a clear and intuitive manner. Maps are constructed by combining and integrating information from intracardiac electrograms with the respective endocardial locations. Like the CARTO™ Cardiac Navigation

## **SECTION 5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

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systems (K992968, K993729, K000248, K000190, K013083, and K020863), all commercially available Biosense Webster catheters equipped with the proprietary location sensor(s) that provide(s) real-time information on the location of the catheter can be used with the NOGA™ XP Cardiac Navigation System.

The current NOGA™ Cardiac Navigation System software was upgraded to allow for:

- on-screen visualization of the catheter shaft,
  - reduction of the steps required to create electromechanical maps
    - NOGA™ XP software creates the equivalent of a 50-point map with only 8-10 contact points, and
    - easier mapping of transient events.
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### **INDICATION FOR USE:**

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The intended use of the NOGA™ XP Cardiac Navigation System with QwikMap™ Software is catheter-based cardiac mapping.

The NOGA™ XP Cardiac Navigation System with QwikMap™ Software allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, cardiac chamber geometry maps, cardiac dynamic maps, cardiac hemodynamic maps, and cardiac electromechanical maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.

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### **PERFORMANCE DATA:**

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The non-clinical bench and animal testing confirms that the NOGA™ XP Cardiac Navigation System with QwikMap™ Software is as safe and as effective as the previously marketed device to which it is being compared and does not raise any new questions of safety or effectiveness.

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### **BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:**

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The indications for use for the NOGA™ XP Cardiac Navigation System with QwikMap™ Software are the same as the indications for use for the predicate devices. Software validation, simulated use, and testing in the porcine model demonstrate that the NOGA™ XP Cardiac Navigation System with QwikMap™ Software works in an equivalent manner to the predicates.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 9 2006

Biosense Webster, Inc.  
c/o Ms. Sigi Caron  
MedTech Consultants, Inc  
2400 Via Carrillo  
Palos Verdes Estates, CA 90274

Re: K053194  
Trade Name: Noga™ XP Cardiac Navigation System with QwikMap™ Software  
Regulation Number: 21 CFR 870.1425  
Regulation Name: Programmable Diagnostic Computer  
Regulatory Class: Class II (two)  
Product Code: DQK  
Dated: February 16, 2006  
Received: February 21, 2006

Dear Ms. Caron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

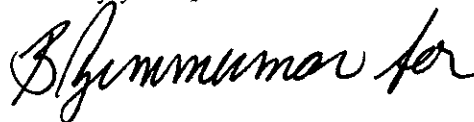
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## SECTION 4.

## INDICATIONS FOR USE STATEMENT

### 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

K05-3194

Device Name: **NOGA™ XP Cardiac Navigation System with QwikMap™ Software**

The intended use of the NOGA™ XP Cardiac Navigation System with QwikMap™ Software is catheter-based cardiac mapping.

The NOGA™ XP Cardiac Navigation System with QwikMap™ Software allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, cardiac chamber geometry maps, **cardiac dynamic maps, cardiac hemodynamic maps, and cardiac electromechanical maps**. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. J. Zimmerman  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K05-3194

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